

REMARKS

Claims 1, 6, 7, 13, 15 and 23 are amended. Claim 14 is cancelled. Claims 1-10, 12-13, 15 and 18-23 are pending in the application.

Claims 1-10, 12-15 and 18-23 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor had possession of the claimed invention at the time the application was filed. Claims 1-10, 12-15 and 18-23 additionally stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner refers back to reasons of record set forth in the Office Action dated September 9, 2002 for the basis of the § 112 rejections.

In the September 9, 2002 Office Action, the Examiner indicates that claim 1-10, 13-15 and 18-23 are rejected because such claims read on any modification of human coagulation factor VIII and indicates that such are therefore not adequately described in the specification as filed. The Examiner further indicates that the claim breadth is not enabled due to the number of fragments and/or modifications possible. Without admission as to the propriety of the any of the Examiner's rejections, independent claims 1, 6 and 23 are amended to recite a full length sequence encoding human coagulation factor VIII. Independent claims 1, 6 and 23 are fully enabled by the specification and reasonably convey to one skilled in the relevant art that the inventor had possession of the claimed invention at the time the application was filed. Accordingly, applicant respectfully requests withdrawal of the § 112 rejection of independent claims 1, 6 and 23 and their corresponding dependent claims 2-5, 7-10 and 18-22 in the Examiner's next action.

Dependent claim 7 is amended to properly depend from claim 6 and is allowable as indicated above. Dependent claim 14 is cancelled.

With respect to claim 12, the Examiner indicates that such is included in the instant § 112 rejection since it remains drawn to any active coagulation factor VIII and is not limited to the specific full length human coagulation factor VIII shown in the instant specification. Applicant notes that as previously amended in response to the September 9, 2002 action, claim 12 recites introducing a sequence encoding human coagulation factor VIII wherein said sequence encodes a full length of said human coagulation factor VIII. Accordingly, independent claim 12 is not drawn to "any active human coagulation factor VIII" as indicated by the Examiner in the present Action. Since claim 12 clearly recites a sequence encoding a full length of human coagulation factor VIII, which was indicated as being allowable by the Examiner at page 2 of the September 9, 2002 Action, claim 12 is allowable.

Independent claim 13 is amended to place it in independent form. Claim 13 recites introducing a sequence encoding human coagulation factor VIII into a plant expression vector, the encoding sequence encoding a full length of said human coagulation VIII deleting a B-domain, and obtaining the B-domain deletion form of human coagulation factor VIII. The Examiner indicates that the B-domain deletion form of human coagulation factor VIII was not described in the specification in such a way such that one skilled in the art would have recognized that applicant contemplated or had possession of such variant at the time the invention was made (present action page 6).

Applicant notes that obtaining the B-domain deletion was clearly contemplated at the time the application was filed as evidenced by the recitation of such in original claim 13. Applicant has amended the specification to add a paragraph which indicates a sequence encoding human coagulation factor VIII protein with the portion encoding the B-domain deleted. The added paragraph additionally sets forth a coding polynucleotide sequence

having the A2 epitope of human coagulation factor VIII replaced with an analogous porcine sequence, and two partial sequences which encode the human factor VIII heavy chain and the human factor VIII light chain. These additional sequences were clearly contemplated at the time of filing as evidenced by claim 15-17 as originally filed. The added paragraph does not comprise "new matter" since "the claims as filed in the original specification are part of the disclosure and therefore if an application as originally filed contains a claim disclosing material not disclosed in the remainder of the specification the applicant may amend the specification to include the claimed subject matter (MPEP § 2163.06 (III)).

The disclosure of the B-deleted sequence in applicant's specification, along with the information available to one skilled in the art at the time the application was filed (as discussed in applicant's previous response), reasonably conveys to one skilled in the art that the inventor had possession of the invention at the time the application was filed and fully enable one of ordinary skill in the art to make or use the invention without undue experimentation. Accordingly, claim 13 complies with the requirements of § 112.

Referring to claim 15, such has been amended to place it in independent form. Additionally as discussed above, the specification has been amended to describe the subject matter as claimed in claim 15. At page 3 of the present Action, the Examiner acknowledges that the subject matter of claim 15 which recites a porcine/human chimera coagulation factor VIII is enabled by the specification. Accordingly, claim 15 complies with the requirements of § 112, first and second paragraphs.

For the reasons discussed above, pending claims 1-10, 12-13, 15 and 18-23 are allowable. Accordingly, applicant respectfully requests formal allowance of such pending claims in the Examiner's next action.

Respectfully submitted,

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